

PM 32

52-150

5-11-98

1 of 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 11 1998

Charles Good
West Chemical Products, Inc.
West Penetone Corporation
74 Hudson Avenue
Tenafly, NJ 07670

Subject: Tamed Iodine Wescodyne
EPA Registration No. 52-150
Submission Dated April 16, 1998

Dear Mr. Good:

The Agency informed your Company on October 24, 1988 that efficacy for the product cited above was deficient. On February 2, 1998, we reminded you of your need to complete efficacy data. We appreciate your willingness to comply at this time by conducting additional efficacy tests. However, given the time frame, the Agency feels compelled to remove all disinfection claims from your label until acceptable data can be generated and reviewed.

The labeling referred to above submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable subject to the comments listed below. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

Labeling:

1. Remove the following statements from the label:
 - a. Germicide for Hospital Use - above the ingredients statement
 - b. WESCODYNE acts rapidly, killing M. Tuberculosis, types I, II, III of the polio virus, Hemolytic Staphylococcus, Streptococcus, Trichophyton Interdigitales, Pseudomonas aeruginosa and other pathogenic bacteria.
 - c. WESCODYNE is its own indicator of germicidal activity.

CONCURRENCES							
SYMBOL	7510W						
SURNAME	Mitchell						
DATE	5-7-98						

- d. Just as long as color remains in this solution, complete and rapid germicidal action is assured.
2. Under the Directions for Use remove:
 - a. The term **disinfecting** from the phrase "For cleaning and **disinfecting** in a single operation..."
 - b. **Surgical and other hospital instruments and equipment.** Prior to disinfection, preclean all equipment and instruments using a detergent solution followed by water rinse. Use 3 ounces (90cc) of WESCODYNE to 5 gallons of water (75 ppm titratable iodine) for thermometer disinfection, isolation and terminal disinfection procedures, disinfection of surgical and other hospital instruments, rubber sheets and rubber gloves, tubing and catheters (max of 5 minutes contact recommended). Make sure to flush and fill the lumen of hollow instruments/equipment with WESCODYNE solution, avoiding entrapment of air bubbles. WESCODYNE may also be used at the same dilutions as a disinfectant and cleaner in housekeeping and procedures including hospital morgues, animal rooms and cages, laboratories and laboratories, and it may also be used in operating room for cleaning and disinfecting inanimate surfaces.
 3. On the front panel, place the statement "**Keep Out of Reach of Children**" immediately above the signal word "**CAUTION.**"
 4. The ingredient statement for this product should declare:

Active ingredient:
 Iodine*.....1.6%
 Inert ingredients:.....98.4%

*From Polyethoxypolypropoxypolyethoxyethanol and Nonylphenoxy-polyethoxyethanol - iodine complexes.

Product Chemistry:

1. Resubmit a revised updated Confidential Statement of Formula (CSF).

 The Confidential Statement of Formula dated 4-16-98 is not complete. Enter the amount of each ingredient in column 14 of the CSF. Submit the EPA Registration Number for the source of your Active Ingredient. If the source for the Active Ingredient is not a registered then submit manufacturing process and the concentration of titratable iodine in the source for the active ingredient and in the formulated end use product.

A stamped copy of your labeling is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 308-6345.

Sincerely,



Robert S. Brennis
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7504C)

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

"tamed iodine"[®]

wescodyne[®]

~~DETERGENT-GERMICIDE FOR HOSPITAL USE~~

ACTIVE INGREDIENTS:

Iodine* 1.6%

INERT INGREDIENTS: 98.4%

*From Polyethoxypolypropoxypolyethoxyethanol and Nonylphenoxy-polyethoxyethanol-iodine complexes

EPA Reg. No. 52-150 EPA EST. 054612-CN001

U.S. PATENT NOS. 3023299, 2931777

CAUTION: KEEP OUT OF REACH OF CHILDREN

MANUFACTURED BY

See Statement of Practical Treatment on Back Panel

WEST CHEMICAL PRODUCTS, INC.

GENERAL OFFICES: 74 Hudson Avenue, Tenafly, NJ 07670

EMERGENCY PHONE NUMBERS: CHEMTREC 1-00-424-9300 OR

WEST CHEMICAL PRODUCTS 1-201-567-3000

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAY 11 1988

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 52-150

~~WESCODYNE acts rapidly, killing M. Tuberculosis, types I, II, III of the polio virus, Hemolytic Staphylococcus, Streptococcus, Trichophyton interdigitale, Pseudomonas aeruginosa and other pathogenic bacteria. It is considered non-selective in its action. WESCODYNE is its own indicator of germicidal activity. In use dilution it has a rich amber color. Just as long as color remains in this solution, complete and rapid germicidal action is assured. If loss of color occurs, or if solution becomes diluted or soiled, discard immediately.~~

STATEMENT OF PRACTICAL TREATMENT:

EYE CONTACT: Flush eyes with large amounts of water. See physician immediately.

SKIN CONTACT: Flush skin with large amounts of water. Remove contaminated clothing and launder before reuse. If skin irritation develops or persists, call physician.

INHALATION: Remove person to fresh air. Administer oxygen or artificial respiration as needed. Call a physician immediately.

INGESTION: If swallowed, give plenty of water or milk. Do not induce vomiting. Call a physician immediately.

STORAGE AND DISPOSAL

STORAGE: Keep container closed when not in use. Do not store below 32°F or above 100°F for extended periods.

DISPOSAL: Do not contaminate water, food, or feed by storage or disposal, or cleaning equipment. In case of spill, flood area with large quantity of water, washing to sewer or collection vessel. Wasters resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Do not reuse empty container. Triple rinse, puncture and dispose of container in a sanitary landfill or by incineration.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant

CLASSIFIED BY UNDERWRITERS' LABORATORIES, INC. AS TO ELECTRICAL CONDUCT AND SPONTANEOUS HEATING ONLY. SEE UL INDEX OF CLASSIFIED PRODUCTS. WESCODYNE CONDUCTIVE FLOORINGS OF THE VINYL TYPE.

Discharge Elimination authority has been notified. Effluent containing this product must be notified the local sewer authority and contact your State Water

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. No soap or other cleaning agent should be used. For cleaning and disinfecting surfaces, use 5 gallons of water (1 part iodine). Use a scrub brush. Surfaces difficult to clean surface soils, preclean with water, then clean using WESCODYNE solution.

~~Surgical and other disinfection, preclean solution followed by water to 5 gallons of water disinfection, isolation of surgical and other gloves, tubing and catheters. Make sure to flush with WESCODYNE solution. WESCODYNE may be used in housekeeping animal rooms and cages used in operating rooms. WESCODYNE is recommended. WESCODYNE is not adversely affected by WESCODYNE is an excellent~~